



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/581,903

06/07/2006

Mario Mellado

21910-00016-US2

1630

30678

7590

01/29/2009

CONNOLLY BOVE LODGE & HUTZ LLP
1875 EYE STREET, N.W.
SUITE 1100
WASHINGTON, DC 20006

EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

01/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,903	Applicant(s) MELLADO ET AL.	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 17-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.9

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 17-27 are drawn to a method of treatment of a mammal suffering from HIV, a retroviral infection genetically related to HIV, or AIDS which comprises treating said mammal with a therapeutically effective amount of one or more agents capable of inhibiting protein isoprenylation, or a pharmaceutically acceptable salt, solvate or derivative thereof.

Group II, claim(s) 28-29 are drawn to a method of treatment of a mammal suffering from HIV, a retroviral infection genetically related to HIV, or AIDS by preventing the accumulation of HIV receptors in raft domains comprising providing a non-raft targeted mutant cytokine receptor.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Schoub, B., Update, A South African Information and Service Centre, The Diana Princess of Wales HIV Research Foundation, printed pages 1-4, especially 1st paragraph, page 1 teach antiretroviral therapy is complex and recommendations are continually being revised in line with current understanding of the pathophysiology of HIV infection. Data from various clinical trials and especially recent evidence of the potent impact of

Art Unit: 1617

combinations of drugs, and also the increasing availability of monitoring tools, especially HIV-RNA viral load tests, continually modify treatment protocols.

.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claim 17- agent capable of inhibiting protein isoprenylation i) pharmaceutically acceptable salt ii) solvate, or iii) derivative thereof. Applicants are required to elect one specific and exact species from (i-iii).

Claim 18- The method of claim 9 further comprising administering to the patient a pharmaceutically effective amount of at least one agent selected from the group consisting of an antiviral agent, a chemokine receptor modulatory agent, a raft domain inhibitory agent, a cholesterol reducing agent, a protein prenylation reducing agent, a Rho-A GTPase inhibitor, and a glycosphingolipid reducing agent. Applicants are required to elect one specific and exact species from (i-iii).

Claim 19-(Currently amended) The method of claim 17, wherein in the one or more agents is admixed with a pharmaceutically acceptable carrier, binder, filler, vehicle, diluent, or excipient or any combination thereof. Applicants' are required to elect one specific and exact species.

Claim 20, 22, - antiviral agent species

Claim 21- a glycosphingolipid species

Claim 23 and 24 - raft domain inhibitory agents. Applicants' are required to elect either the limitations of claim 23 or 24.

Claim 27 – Applicants' are required to elect an interval of treatment with either the use of one or more of the agents.

Claim 28- Applicants' are to elect i) a method of treatment of a mammal suffering from HIV, ii) a retroviral infection genetically related to HIV, iii) or AIDS by preventing the accumulation of HIV receptors in raft domains comprising providing a non-raft targeted mutant cytokine receptor.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

Art Unit: 1617

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 17- agent capable of inhibiting protein isoprenylation i) pharmaceutically acceptable salt ii) solvate, or iii) derivative thereof. Applicants are required to elect one specific and exact species from (i-iii).

Claim 18- The method of claim 9 further comprising administering to the patient a pharmaceutically effective amount of at least one agent selected from the group consisting of an antiviral agent, a chemokine receptor modulatory agent, a raft domain inhibitory agent, a cholesterol reducing agent, a protein prenylation reducing agent, a Rho-A GTPase inhibitor, and a glycosphingolipid reducing agent. Applicants are required to elect one specific and exact species from (i-iii).

Claim 19-(Currently amended) The method of claim 17, wherein in the one or more agents is admixed with a pharmaceutically acceptable carrier, binder, filler, vehicle, diluent, or excipient or any combination thereof. Applicants' are required to elect one specific and exact species.

Claim 20, 22, - antiviral agent species

Claim 21- a glycosphingolipid species

Claim 23 and 24 - raft domain inhibitory agents. Applicants' are required to elect either the limitations of claim 23 or 24.

Claim 25- Applicants' are to elect whether the chemokine receptor modulator i) inhibits formation and/or ii) disassociates membrane raft domains.

Claim 27 – Applicants' are required to elect an interval of treatment with either the use of one or more of the agents.

Claim 28- Applicants' are to elect i) a method of treatment of a mammal suffering from HIV, ii) a retroviral infection genetically related to HIV, iii) or AIDS by preventing the accumulation of HIV receptors in raft domains comprising providing a non-raft targeted mutant cytokine receptor.

The following claim(s) are generic: 17-25, and 27-28.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/

Primary Examiner, Art Unit 1617

Application/Control Number: 10/581,903
Art Unit: 1617

Page 8

TEB